510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR 807.87, 21 CFR 807.92, Format for Traditional and Abbreviated 510(k)s.

1. Name of Submitter, Contact Person and Date Summary Prepared:

OCT - 5 2006

Applicant:	Edgar Otto Chairman of the Board Preferred Medical Devices, Inc. 6400 Congress Avenue, Suite 1700 Boca Raton, FL 33487
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Contact:	Penelope Greco MedApprove, Inc.
Phone:	508.843.0282
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Date of Preparation:	September 25, 2006

2. Device Trade Name and Common Name:

Trade Name:	UrAssist
Common/Usual Name:	Urine Collector and accessories
Regulation Number:	21 CFR 876.5250

3. Device Class: Class 1

4. Legally Marketed Equivalent Device Names: Hollister Urinary Drainage Collectors
Hollister Urinary Leg Bags

5. Performance Standards:
UrAssist will comply with applicable parts of IEC 60601-1 and IEC 60601-1-2 Prior to release in the US market.

6. Description of the Device:
UrAssist is a portable urine collection unit which utilizes a battery-operated pump-assisted technology to drain the urine from a collection cup through a plastic tube and into a collection bag that stores a day's amount of urine.

7. Intended Use of the Device:
The UrAssist system is intended for the non-invasive, non-sterile collection of urine.

8. Comparison of technological characteristics with Predicate Device:
The primary difference between Urassist and urine collections units already legally marketed as Class 1 devices is that the Urassist system includes a battery-operated pump that drains urine from a collection cup through a tube and into a receptacle (collection bag). Legally marketed urine collection systems rely on gravity for drainage through tubing and into a collection bag.

9. Discussion of Non-clinical Studies:
Biocompatibility, EMC and electrical safety testing, as well as in-house testing verify or will verify that UrAssist meets the requirements specified for a urine collection unit.

10. Conclusion:
The UrAssist System is safe and effective and affords individuals who rely on urine collection systems, a safe, clean, concealed method to store a day's worth of urine.

Preferred Medical Devices
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 5 2006

Preferred Medical Devices, Inc.
c/o Ms. Penelope H. Greco
MedApprove
8 Gray Lodge Road
KITTERY ME 03904

Re: K062061
Trade/Device Name: UrAssist
Regulation Number: 21 CFR §876.5250
Regulation Name: Urine collector and accessories
Regulatory Class: I
Product Code: NZU
Dated: August 30, 2006
Received: August 31, 2006

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

'Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K062061

Device Name:

Indications for Use:

The UrAssist system is intended for the non-invasive, non-sterile collection of urine.

Prescription Use_____ OR Over-The-Counter Use_√___
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062061

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